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Building Quality in Pharmaceutical Products

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A B S T R A C T

Pharmaceutical Quality is widely impacted by the type and quality of starting materials, manufacturing procedure, packaging, shipping and storage terms, and other factors. These factors can influence accumulatively. If a pharmaceutical product does not meet recognized quality standards, passes its expiration date, or has been degraded by storage requirements, the possible outcomes could be:

- Lack of therapeutic effect, leading to protracted illness or mortality
- Toxic and adverse effects
- Depletion of financial resources
- Loss of trustworthiness of the health care organization.

Manufacturing organizations must balance the costs of establishing and maintaining quality assurance systems against the benefits of having safe and effective medicines.

Keywords: Active Pharmaceutical Ingredients, Quality Assurance, Pharmaceutical Quality, GMP, Quality Requirements, Pharmaceutical Attributes, Excipients, Quality Conformance, Consistency, Therapeutic, Monitoring and Pharmacovigilance.

1. Introduction

The quality of a Pharmaceutical product is determined by the key starting materials, Active Pharmaceutical Ingredients, Excipients, Equipment, and technical know awareness that go into producing and packaging it. Unlike other manufacturing, a medication is an active product whose color, consistency, weight, and chemical identity can get affected between manufacturing and end user consumption. A medicine that passes all laboratory tests may be futile within a few months if the product could not maintain its purity and character.

The purpose of building quality in pharmaceutical product is to help ensure that each medicine reaching a patient is safe, effective, and of appropriate quality. The quality of pharmaceutical products is ensured by the technical and managerial activities of the quality system, which includes evaluating pharmaceutical product documentation, performing, or reviewing quality-control laboratory tests, and monitoring product performance.

Quality is very important in each stage of life cycle of Pharmaceutical Product. Quality cannot be analyzed into the corresponding stage, rather building-in quality from the development stage and all the way through a product's lifecycle will produce an ideal quality product.

Quality is one of the most important attribute in the pharmaceutical industry. Governing organizations like European Union, Medicines and Healthcare products Regulatory Agency, Therapeutic Goods Administration, United States Food and Drug Administration, International Council for Harmonization, World Health Organization, Central Drugs Standard Control Organization etc. expect the best quality in drug products. Pharmaceutical quality can be characterized and examined in many ways. Quality requirements are announced continually in pharmacopoeias and in many government/ regulatory journals, which provide detailed descriptions of pharmaceutical attributes and analytical techniques. Requirements may vary slightly from one pharmacopoeia to another. A particular medicament may meet the standards of one pharmacopoeia and not of an alternative. When specifications have not

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been established, as is usually the case for freshly promoted pharmaceuticals, analytical methods developed by the producer and submitted as a part of marketing authorization application requirements are generally applied.

The key consumer countries publish their own pharmacopoeias, like the European Pharmacopoeia (by EU), The International Pharmacopoeia (by WHO), the U.S. Pharmacopeia (by US), and the British Pharmacopoeia (by UK) are used frequently.

Ensuring that pharmaceuticals are produced, packaged, and stored in a controlled, uncontaminated environment is a vital part of the quality assurance process. During production and storage, medicines must remain free from impurities, contaminants, and foreign material. Toxic materials must be restricted to prevent their cross-contaminating to other medicines in nearby areas or leaking into the open-air environment. HVAC systems make this possible by maintaining the proper temperature, humidity and air circulation for medicines and equipment used during manufacturing and storage.

1.1. Key attributes like Identity, Purity, Strength or Potency, Uniformity of the dosage form, bioavailability, and stability are important that are considered in the specifications for evaluating the quality of pharmaceutical product.

Identity: The identity test should confirm the presence of correct active ingredient(s) specified on the label. This feature is generally the easiest way to check the product.

Purity: Adding up to the API, most pharmaceuticals are composed of excipients added for improving physical characteristics, adding bulk, consistency, or color that should not contain potentially toxic impurities or microbes. The product should not have significant measures of other products via cross-contamination.

Strength/ Potency: The medicine should contain the declared amount of API. Harmful degradation products must be absent or should be below defined limits. Most pharmacopoeias indicate an average content range, such as 95 to 105 percent of the quantity mentioned on the label, rather than an exact amount. To ensure a long shelf life, manufacturers often produce pharmaceuticals with the maximum allowable amount, which provides a scope of safety for slight losses in strength or potency with time.

Uniformity of Dosage Units: The consistency, color, shape, and dimensions of tablets, capsules, creams, and solutions should not differ from one dose to the another. Any deficiency of uniformity may indicate problems with other quality factors such as identity, purity, or strength/ potency. Lack of dosage consistency may not impact the safety or efficacy of a drug, but it does indicate a lack of controls over GMP, which could influence the suitability of a product.

Bioavailability: Bioavailability implies to the pace and totality with which a pharmaceutical administered in any dosage form like tablet, capsule, injection, sub lingual etc. enters the bloodstream. The bioavailability of a product may vary with the other excipients used in the formulation, such as solvents, binders, coloring agents, and coating material. How the formulation is designed. The relative bioavailability of two drugs is especially critical when a drug product that is normally purchased from one producer is swapped with a product containing the same drug substance in the similar dosage form, and in the similar quantity, but produced by a different organization. Even though the products comprise of the correct quantity of the API, the formulation may not give the anticipated curative results if the API is released too swiftly, too gradually, or partly when they are matched. Two pharmaceuticals are believed to be bioequivalent and may be used interchangeably if mutually are engrossed into the bloodstream at the same rate and to the same magnitude.

Stability: A drug product must retain its properties within specified limits, at a particular storage condition. The manufacturer and the country's drug controlling authority established time that a pharmaceutical's stability is under assurance, shall end with the expiration date. A product's stability differs with the input active ingredient, which can be further affected by its formulation and packing. Non-suitable storage and supply can cause physical deterioration and chemical degradation, reduced strength, and sporadically formation of toxic degradation products. These impacts are likely to occur under conditions of high temperature and humidity.

1.2. Determinants of Pharmaceutical Quality

The quality of a medicinal product manufactured on production line is established by the start-up materials, unit's environment, manufacturing paraphernalia, and technical understanding implied during development and manufacturing of the medicines. The medicines that eventually reaches the end user, is further affected by packaging and by shipping and storage terms. These impacts, especially factors in the manufacturing process, can be aggregate. For example, the excipients used to give tablets bulk and uniformity may not affect the color, texture, or chemical quality of a drug product until the immediate container is opened in a hot, tropical environment. Then, differing on the ingredients, the tablet may remain secure and dry or become damp and deteriorate within a matter of days. Humidity at manufacturing unit during packaging may also affect quality. If oral rehydration product packs are not packaged in an exceptionally low-humidity environment, dampness enters the packet and may result in chemical or physical alterations in the mixture that make it hard to use. Likewise, the extent of crushing, diligence of mixing, selection of packaging, upkeep of packaging apparatus, and other aspects can have an effect that may not exist until the drug product reaches the point of utilization.

1.3. Pragmatic Methodologies to Quality Assurance

The procedures to establish a thorough quality assurance program can be distributed into three types:
1. Techniques to ensure that only medicine/ drug products that meet current benchmarks for quality are bought These comprise of:
   a. Product choice
   b. Raw material provider selection
   c. Certificate of analysis for each lot of the material.
   d. Certification of GMP/ conformance
   e. Batch endorsement
   f. Insertion of detailed product quality terms

2. Techniques to verify that dispatched goods complying with the requirements. These comprise of:
   a. Pre- and post-delivery assessment
   b. Methodical pharmaceutical analysis

3. Systems to examine and preserve the quality of pharmaceuticals from the instant they are collected until the medicine is finally consumed by the end user. These comprise of:
   a. Appropriate storage and dissemination practices
   b. Suitable dispensing
   c. Instructions to the end user on appropriate use of medications
   d. Product imperfection and pharmacovigilance coverage programs

Few pharmaceutical administration systems can efficiently manage all the potential quality assurance events for all the drug products that are procured. Subsequently, reasonable objectives must be set to identify the blend of administrative and technical quality assurance events that will be most efficient under prevailing situations.

Sustaining Pharmaceutical Quality
Sustaining medicine quality requires meticulous consideration to storage terms and transport.Procedures to help sustain pharmaceutical quality start with proper storage conditions at the interface and timely release.

Monitoring pharmaceutical Quality
Even though after implying every endeavor, faulty products seldom slip through, and the quality of even the finest produced drug product may decline. Moreover, health care personnel and patients likewise may have flawed perceptions that only branded products from trendsetter firms are of excellent quality, specifically when generic manufactured goods are not well established and recognized.

Product Problem Reporting
Instituting a nationwide product problem coverage system is crucial so that health personnel can inform presumed or established problems with specific pharmaceutical drug products. Product problem reporting ought to be the part of a global pharmacovigilance system, which also comprises checking and reporting adverse drug incidents and medication miscalculations.

Goods Recalls
Pharmaceutical products found to be faulty should be withdrawn swiftly. The quality assurance unit in the country's drug regulatory body should develop specific procedures for carrying out the recall. Prompt action helps avoid unjustified exposure once the crisis has been identified.

Product and process knowledge shall be controlled and amended from development across the commercial life of the product up to product termination. Expertise management shall be done with a methodical methodology for obtaining, evaluating, collecting, and distributing material associated with the products, manufacturing practices and modules. Sources of expertise shall include, previous understanding, pharmaceutical development experiments, technology transmission, process validation studies over the product lifecycle, manufacturing knowledge, innovation, persistent improvement, and change controlling activities. This shall be implemented by using suitable statistical and evaluation like Critical process parameters, Critical quality attributes, Product profile, Critical material attributes, Quality Risk Assessment, Design Control, Control Approach and Lifecycle Administration and Continual improvement.

2.Conclusion

Quality is an extensively shared obligation. The Pharmaceutical organizations need to ascertain the obligations for the review and safeguarding of Pharmaceutical Quality at all stages. If a product become ineffectual or hazardous by the time it reaches the end user, then all other endeavors of the system will be considered futile.Suitable components of manufacturing process controls to produce pharmaceutical products for human and animal use shall be adequately controlled and ensured, including (not limited to) Key Starting Material, Active Pharmaceutical Ingredients, Processes, Procedures, Monitoring etc.

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